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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/615,668	07/08/2003	Antonello Covacci	CHIR-0337	6533
7590 Chiron Corporation Intellectual Property PO Box 8097 Emeryville, CA 94662-8097				
			EXAMINER DEVI, SARVAMANGALA J N	
			ART UNIT 1645	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary**Application No.**

10/615,668

Applicant(s)

COVACCI ET AL.

Examiner

S. Devi, Ph.D.

Art Unit

1645

Period for Reply -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 February 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68 and 70-72 is/are pending in the application.
- 4a) Of the above claim(s) 71 and 72 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68 and 70 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

RESPONSE TO APPLICANTS' AMENDMENT

Applicants' Amendment

- 1) Acknowledgment is made of Applicants' amendments filed 02/19/08 in response to the non-final Office Action mailed 11/16/07.

Status of Claims

- 2) Claims 38-40, 44, 48-50, 54, 56-59, 62, 64, 65 and 68 have been amended via the amendment filed 02/19/08.

Claims 63, 66, 67 and 69 have been canceled via the amendment filed 02/19/08.

New claims 70-72 have been added via the amendment filed 02/19/08.

Claims 71 and 72 are withdrawn have been withdrawn from consideration as not being directed to the elected species. See 37 C.F.R. 1.142(b) and M.P.E.P. § 821.03.

Claims 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68 and 70 are under examination.

Substitute Sequence Listing

- 3) Acknowledgment is made of Applicants' substitute sequence listing which has been entered on 03/03/08.

Prior Citation of References

- 4) The references cited or used as prior art in support of one or more rejections in the instant Office Action and not included on an attached form PTO-892 or form PTO-1449 have been previously cited and made of record.

Objection(s) Withdrawn

- 5) The objection to the specification made in paragraph 7(b) of the Office Action mailed 04/09/07 and maintained in paragraph 7 of the Office Action mailed 11/16/07 is withdrawn in light of Applicants' amendment to the specification.
- 6) The objection to the specification made in paragraph 8 of the Office Action mailed 11/16/07 is withdrawn in light of Applicants' cancellation of claims 63 and 66 and Applicants' amendment to claim 68.

Art Unit: 1645

May, 2008

- 7) The objection to claims 56 and 59 made in paragraph 36 of the Office Action mailed 11/16/07 is withdrawn in light of Applicants' amendment to the claims.

Objection to Specification

- 8) The instant specification is objected to for the following reason:

37 CFR 1.75(d)(1) provides, in part, that 'the terms and phrases used in the claims must find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description.'

Claim 68, as amended, is drawn to an isolated polynucleotide encoding a polypeptide comprising one or two amino acid sequences of SEQ ID NO: 10 and one or two amino acid sequences of SEQ ID NO: 9. What is claimed in these new claims lacks clear support or antecedent basis in the specification.

Rejection(s) Moot

- 9) The rejection of claims 63 and 66 made in paragraph 9 of the Office Action mailed 04/09/07 and made/maintained in paragraph 20 of the Office Action mailed 11/16/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the co-pending application 11/580,632, is moot in light of Applicants' cancellation of the claims.

- 10) The rejection of claims 63 and 66 made in paragraph 35 of the Office Action mailed 11/16/07 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (*PNAS* 90: 5791-5795, June 1993, already of record), is moot in light of Applicants' cancellation of the claims.

- 11) The rejection of claims 63 and 66 made in paragraph 33 of the Office Action mailed 11/16/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is moot in light of Applicants' cancellation of the claims.

Rejection(s) Maintained

- 12) The provisional rejection of claims 38-40, 44, 49, 50, 54, 59, 62, 64, 65 and 68 made in paragraph 9 of the Office Action mailed 04/09/07 and made/maintained in paragraph 20 of the Office Action mailed 11/16/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 39 and 40 of the

Art Unit: 1645

May, 2008

co-pending application 11/580,632, is maintained for reasons set forth therein. Applicants cite MPEP § 804.I.B and state that upon resolution of other grounds of rejection, the obviousness-type double patenting rejection over US application 11580632 should be withdrawn and the present application allowed to issue without a terminal disclaimer.

13) The provisional rejection of claims 38-40, 44, 49, 50, 59, 62 and 65 made in paragraph 10 of the Office Action mailed 04/09/07 and made/maintained in paragraph 20 of the Office Action mailed 11/16/07 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 3, 4, 6 and 7 of US patent 6,090,611 (Applicants' IDS), is maintained for reasons set forth therein. Applicants request that the rejection be held in abeyance pending notification of allowable subject matter in the instant application.

New claim 70 and the amended claim 68 are now added to this rejection.

Rejection(s) Withdrawn

14) The rejection of claims 38-40, 44-46, 48-50, 54, 56-59, 62, 63 and 65 made in paragraph 32 of the Office Action mailed 11/1/07 under 35 U.S.C. § 112, first paragraph, as new subject matter, is withdrawn in light of Applicants' amendment to the claims and/or the base claim.

15) The rejection of claim 68 made in paragraph 33 of the Office Action mailed 11/16/07 under 35 U.S.C. § 112, first paragraph, as containing new matter, is withdrawn in light of Applicants' amendment to the claim.

16) The rejection of claim 68 made in paragraph 34 of the Office Action mailed 11/16/07 under 35 U.S.C § 112, second paragraph, as being indefinite, is withdrawn in light of Applicants' amendment to the claim.

17) The rejection of claims 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65 and 68 made in paragraph 35 of the Office Action mailed 11/16/07 under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (PNAS 90: 5791-5795, June 1993, already of record), is withdrawn in light of Applicants' amendment to the claims and/or the base claim. A

Art Unit: 1645
May, 2008

modified rejection is set forth below that addresses the claims as amended and the new claim.

Rejection(s) Necessitated by Applicants' Amendment

Rejection(s) under 35 U.S.C § 112, First Paragraph (New Matter)

18) Claims 68, 44 and the dependent claims 45, 46, 49, 50, 54, 56 and 57 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Claim 68, as amended, is drawn to 'an isolated polynucleotide encoding a polypeptide comprising one or two amino acid sequences of SEQ ID NO: 10 and one or two amino acid sequences of SEQ ID NO: 9'. Claim 44, as amended, is drawn to an isolated polynucleotide encoding 'a polypeptide comprising wherein said polypeptide comprises one or two amino acid sequences' of SEQ ID NO: 10. Applicants state that exemplary support for the amendment is located in Figure 4 of the specification, which illustrates to one of ordinary skill in the art a polynucleotide encoding a polypeptide comprising SEQ ID NOs: 9 and 10, which sequences are boxed in the depicted amino acid sequence. The claimed polynucleotides encompass polynucleotides other than SEQ ID NO: 4 or parts thereof encoding SEQ ID NO: 9 and/or SEQ ID NO: 10. However, these parts of the specification are not supportive of the generic polynucleotide claimed in the instant claim which encompasses a polynucleotide other than SEQ ID NO: 4. Figure 4 is exclusively supportive of SEQ ID NO: 4 comprising a nucleotide sequence(s) therein that encodes one or two amino acid sequences of SEQ ID NO: 9 and SEQ ID NO: 10, wherein the nucleotide bases outside of the sequences that encode SEQ ID NO: 9 and SEQ ID NO: 10 are from SEQ ID NO: 4. Figure 4 is not supportive of a generic polynucleotide of any microbial or non-microbial origin comprising nucleotide sequences encoding one or two amino acid sequences of SEQ ID NO: 9, and one or two amino acid sequences of SEQ ID NO: 10, but describes specifically the *cai* gene of the G39 strain of *H. pylori* wherein the gene is SEQ ID NO: 4, but not any generic gene. New matter includes not only the addition of wholly unsupported subject matter but also, adding

Art Unit: 1645
May, 2008

specific percentages or compounds after a broader original disclosure, or even omission of a step from a method. See M.P.E.P 608.04 to 608.04(c).

Applicants are respectfully requested to point to the descriptive support in the specification as filed by pointing to specific lines and pages, for the new limitations, or alternatively, remove the new matter from the claim(s). Applicants should specifically point out the support for any amendments made to the disclosure. See MPEP 714.02 and 2163.06.

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

19) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

20) Claims 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68 and 70 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 38 is indefinite and confusing in the recitation: 'at least 15 contiguous nucleotides from SEQ ID NO: 4, wherein said polynucleotide encodes a polypeptide comprising one or two ... SEQ ID NO: 10'. The minimum length requirement of the claimed polynucleotide is 15 contiguous nucleotides from SEQ ID NO: 4, and it is required to include two SEQ ID NO: 10. However, two copies of SEQ ID NO: 10 are ten contiguous amino acids in length. It is unclear how a ten contiguous amino acid-long polypeptide can be encoded by 15 contiguous nucleotides from SEQ ID NO: 4.

(b) Analogous rejection and criticism apply to claim 48 with regard to the limitation: 'at least 15 contiguous nucleotides ...'.

(c) Analogous rejection and criticism apply to claim 44 with regard to the limitation: 'at least five contiguous amino acids from SEQ ID NO: 5, wherein said polypeptide comprises ... two amino acid sequences of SEQ ID NO: 10'.

(d) Claims 39, 40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68 and 70, which depend from claim 38 or 44 are also rejected as being indefinite because of the indefiniteness identified above in the base claim.

Art Unit: 1645
May, 2008

Rejection(s) under 35 U.S.C. § 102

21) The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

22) Claims 68, 44-46, 49, 50, 54, 56 and 57 are rejected under 35 U.S.C. § 102(b) as being anticipated by Covacci *et al.* (*PNAS* 90: 5791-5795, June 1993, already of record).

Instant claim is granted the effective filing date of the instant application because of the new matter identified above.

Covacci *et al.* taught an isolated polynucleotide of SEQ ID NO: 4 encoding one or two amino acid sequences of SEQ ID NO: 10, or an amino acid sequence of SEQ ID NO: 10 and SEQ ID NO: 9 and further encoding an amino acid sequence of SEQ ID NO: 9 or SEQ ID NO: 10; a vector comprising the same, and an isolated host cell transformed with the vector. The prior art polynucleotide encodes the CAI antigen of *Helicobacter pylori* comprising 1-1147 amino acids of the amino acid sequence of SEQ ID NO: 5, which is expected to be immunologically identifiable with the instantly recited amino acid sequence of SEQ ID NO: 5. See Figure 3; Materials and Methods; and Results. The prior art polynucleotide comprises at least one nucleotide sequence of the instantly recited nucleotides 3202-3216 of SEQ ID NO: 4.

Claims 38-40, 44-46, 48-50, 54, 56-59, 62-66 and 68 are anticipated by Covacci *et al.*

23) Claims 68, 44-46 and 56 are rejected under 35 U.S.C. § 102(b) as being anticipated by Peterson *et al.* (*Nature* 354: 369-373, 1991, already of record).

Peterson *et al.* taught an isolated polynucleotide encoding an at least five amino acid-long polypeptide comprising the amino acid sequence of EPIYA (i.e., the instantly recited SEQ ID NO: 10) and *E. coli* cells overexpressing the same. See right column of page 369 and Figure 1. Since the prior art EPIYA sequence is structurally the same as the instantly recited SEQ ID NO: 10 encoded by the claimed polynucleotide, it is

Art Unit: 1645
May, 2008

expected to necessarily serve inherently as a *H. pylori* CAI antigen immunologically identifiable with the instantly recited SEQ ID NO: 5.

Claims 68, 44-46 and 56 are anticipated by Peterson *et al.*

Remarks

24) Claims 38-40, 44-46, 48-50, 54, 56-59, 62, 64, 65, 68 and 70 stand rejected.

25) Applicants' amendment necessitated the new ground(s) of rejection presented in this Office

action. **THIS ACTION IS MADE FINAL.** Applicants are reminded of the extension of time policy as set forth in 37 C.F.R. 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 C.F.R. 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

26) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. The Fax number for submission of amendments, responses and/or papers is (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

27) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.Mov>. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service

Art Unit: 1645
May, 2008

Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

28) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Shanon Foley, can be reached on (571) 272-0898.

/S. Devi/
S. Devi, Ph.D.
Primary Examiner
AU 1645

May, 2008